REMARKS

Claims 15 and 33 have been canceled without prejudice; the subject matter of claim 15 has been included in independent claim 13. Claims 13 and 39 have been amended for greater clarity. The claim amendments are fully supported by Applicants' specification and original claims (e.g., claim 15). No new matter has been introduced. The amendments are made solely to expedite prosecution of the application, and Applicants reserve the right to prosecute claims of similar or differing scope in subsequent applications.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

Applicants thank the Examiner for her helpful suggestions during the telephonic interview dated February 8, 2006.

Claim Rejections under 35 U.S.C. § 102(b)

Claims 13, 15-16, and 32-38 are rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by Ruoslahti et al. (U.S. Patent No. 5,654,270, 1997). Applicants respectfully traverse this rejection.

The standard for anticipating a claim is clearly outlined in MPEP 2131, and this standard is further supported by the Courts. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1978).

Applicants reiterate the arguments already made of record and contend that Ruoslahti et al. fail to satisfy this criteria for anticipating the present invention. Nevertheless, solely for greater clarity, Applicants have amended independent claim 13 to clarify that the biglycan therapeutic potentiates agrin-induced phosphorylation of muscle, skeletal, receptor tyrosine kinase (MuSK) on the cell. Support for the claim amendments can be found throughout the specification (e.g., page 5, lines 8-11; page 12, lines 2-5; page 15, lines 24-25).

By contrast, Ruoslahti et al. neither teach nor suggest a method which involves use of a biglycan therapeutic to potentiate agrin-induced phosphorylation of MuSK. Thus, Ruoslahti et al. fail to meet the limitations of independent claim 13 and thus fail to anticipate the claimed subject matter.

The Examiner alleges that the cited prior art inherently teaches the instant invention. Specifically, the Examiner asserts that "contact of biglycan and cell membrane would lead to activation of MuSK." See Office Action, page 4, lines 15-16.

Applicants respectfully disagree. Inherency cannot be based on probabilities. "In relying upon a theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Ruoslahti et al. merely teach that decorin and biglycan inhibit the cell regulatory functions of TGF-beta proteins, in particular, in dermal scar healing. However, there is no evidence to suggest that dermal scar healing is *necessarily* accompanied by an increase in agrin-induced phosphorylation of MuSK. In fact, throughout the document, Ruoslahti et al. show that increasing the concentration of decorin or biglycan used in an experiment produces a greater inhibition of TGF-beta function. See, e.g., Example III (Figure 4) and Example V (Figure 7) of Ruoslahti et al. Thus, a skilled artisan following the teachings of Ruoslahti et al. would seek to use a high dosage of biglycan for therapeutic purposes. By contrast, the present application teaches that the stimulatory effect of biglycan on agrin-induced phosphorylation of MuSK is biphasic. At high levels, biglycan can inhibit agrin-induced phosphorylation of MuSK. See, e.g., Example 10, page 83. Thus, in following the teachings of Ruoslahti et al., one of skill in the art is unlikely to develop a method for administering a biglycan therapeutic in an amount effective to potentiate agrin-induced phosphorylation of MuSK. Accordingly, the rejection based on the doctrine of inherency should be withdrawn.

In sum, Applicants contend that Ruoslahti et al. fail to satisfy the criteria for expressly or inherently anticipating the claimed invention as recited in independent claim 13 as amended. For

the same reasons, dependent claims 16, 32, and 34-39 are also free of the art. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Rejections under 35 U.S.C. § 112, second paragraph

The examiner has rejected claim 39 for allegedly lacking antecedent basis with respect to claim 13.

Claim 39 is amended to resolve the issue of antecedent basis. Applicants request withdrawal of the rejection.

CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims are now in condition for allowance and early notification to this effect is earnestly solicited. Any questions arising from this submission may be directed to the undersigned at (617) 951-7000. If any other fee is due, please charge our Deposit Account No. **18-1945** from which the undersigned is authorized to draw, under Order No. **BURF-P02-006**.

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Respectfully submitted,

By _____

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